



## ENZYMATIC THERAPY

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P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

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December 21, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

DEC 23 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

| PRODUCT NAME                 | STATEMENTS   | INGREDIENT(S) TO WHICH THE CLAIM REFERS  |
|------------------------------|--|--|
| Cell Forte® Max <sup>3</sup> | Triple-strength Cell Forte Max <sup>3</sup> features an exclusive combination of IP-6 and inositol, maitake D-fraction, and POA Cat's Claw, which are essential in supporting healthy cell development, defending your deep immune health and delivering life-changing results.* | Calcium (from calcium magnesium phytate), Phosphorus (from calcium magnesium phytate), Magnesium (from calcium magnesium phytate), IP-6 (inositol hexaphosphate) (from calcium magnesium phytate), Inositol, Maitake (Grifola frondosa) Mushroom Extract, POA Cat's Claw (Uncaria tomentosa) (pentacyclic chemotype) (Saventaro® brand) Root Extract |

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Michael P. Devereux  
Chief Operations Officer

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| PRODUCT NAME                 | STATEMENTS  | INGREDIENT(S) TO WHICH THE CLAIM REFERS                                  |
|------------------------------|---|--|
| Cell Forte® Max <sup>3</sup> | The patented combo from the original Cell Forte dramatically increases natural killer cell activity and enhances normal cell division.* | IP-6 (inositol hexaphosphate) (from calcium magnesium phytate), Inositol |

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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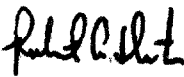
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| <u>PRODUCT<br/>NAME</u>         | <u>STATEMENTS</u>   | <u>INGREDIENT(S) TO WHICH THE<br/>CLAIM REFERS</u> |
|---------------------------------|---|--|
| Cell Forte®<br>Max <sup>3</sup> | Clinically shown to support healthy cell growth and keep your body's immune response healthy and balanced.* | Maitake (Grifola frondosa) Mushroom Extract        |

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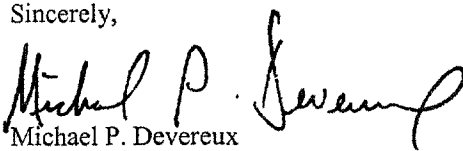
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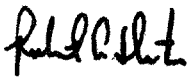
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| <u>PRODUCT<br/>NAME</u>         | <u>STATEMENTS</u>  | <u>INGREDIENT(S) TO WHICH THE<br/>CLAIM REFERS</u>   |
|---------------------------------|--|--|
| Cell Forte®<br>Max <sup>3</sup> | Patented and clinically studied to benefit the natural and acquired immune systems and enhance the protective power of critical B- and T-cells.* | POA Cat's Claw (Uncaria tomentosa) (pentacyclic chemotype) (Saventaro® brand) Root Extract |

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

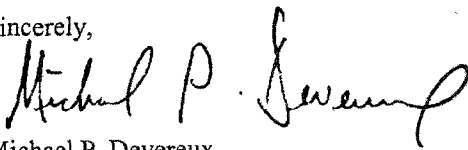
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/21/05

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Michael P. Devereux  
Chief Operations Officer



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| <u>PRODUCT NAME</u>          | <u>STATEMENTS</u>  | <u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>   |
|------------------------------|--|--|
| Cell Forte® Max <sup>3</sup> | The synergistic forces of each power-packed ingredient provide superior support for the most critical cells in your immune system by amplifying your deep immune functions.* | Calcium (from calcium magnesium phytate), Phosphorus (from calcium magnesium phytate), Magnesium (from calcium magnesium phytate), IP-6 (inositol hexaphosphate) (from calcium magnesium phytate), Inositol, Maitake (Grifola frondosa) Mushroom Extract, POA Cat's Claw (Uncaria tomentosa) (pentacyclic chemotype) (Saventaro® brand) Root Extract |

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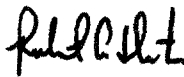
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|---------------------------------|---|--|
| Cell Forte®<br>Max <sup>3</sup> | The clinically studied combination of ingredients found only in Cell Forte Max <sup>3</sup> have triple the power to dramatically enhance your immune system and give you ultimate power to prevail.* | Calcium (from calcium magnesium phytate), Phosphorus (from calcium magnesium phytate), Magnesium (from calcium magnesium phytate), IP-6 (inositol hexaphosphate) (from calcium magnesium phytate), Inositol, Maitake (Grifola frondosa) Mushroom Extract, POA Cat's Claw (Uncaria tomentosa) (pentacyclic chemotype) (Saventaro® brand) Root Extract |

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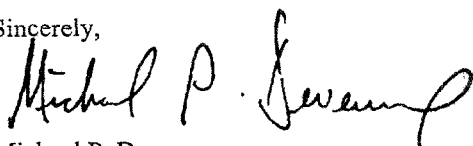
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| Cell Forte®<br>Max <sup>3</sup> | POA Cat's Claw extract, as found in Cell Forte Max <sup>3</sup> , has been clinically shown to significantly increase activity of key immune cells-T and B cells- by up to 137% and 82%, respectively, to provide optimum deep immune support.* | POA Cat's Claw (Uncaria tomentosa) (pentacyclic chemotype) (Saventaro® brand) Root Extract |

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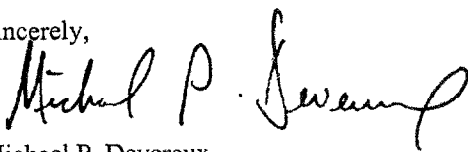
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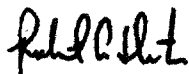
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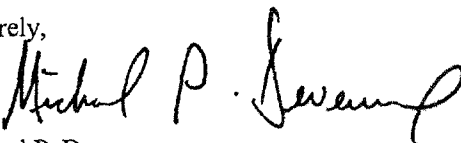
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